

REMARKS

Claim 1 is amended herein. Support for the amendment can be found in the specification at page 7, lines 19-20 and 24-28, and at page 8, line 12.

REJECTION UNDER 35 USC §112, ¶2

The examiner rejects claim 6 as indefinite. Applicants respectfully point out to the examiner that claim 6 is drawn to a solid dosage form obtained by a process as claimed in claim 1. The active ingredient is introduced into the process in uncomplexed form, and yet as a result of the claimed process, a cyclodextrin/active ingredient complex is formed. Thus, the resulting dosage form contains complexed active ingredient.

REJECTION UNDER 35 USC §102(E)

The examiner rejects claims 1, 2, and 5-6 under 35 USC §102(e) as anticipated by Stella et al. (US 6,046,177). The present claims do not include formulations in which sulfoalkyl ether cyclodextrins are employed. Stella '177 requires these cyclodextrins in particular. Accordingly, Stella '177 does not anticipate the present claims.

REJECTIONS UNDER 35 USC §103(A)

The examiner rejects claims 3-4 under 35 USC §103(a) as obvious over Stella '177 in view of Klimesh et al. (US 4,880,585), and claims 1, 2, and 5-6 as obvious over Stella et al. (US 5,874,418) in view of Stella '177. As indicated above, the disclosure of Stella '177 does not read on the presently amended claims. Further, as Stella '418 also utilizes sulfoalkyl ether cyclodextrins exclusively, that reference does not read on the

present claims.

Additionally, both Stella references emphasize the advantages of using these cyclodextrins, and discuss problems and disadvantages of using other mixtures of (different) cyclodextrins and active ingredients. One of skill in the art would view both Stella references to require sulfoalkyl ether cyclodextrins, and would not be motivated to employ other types of cyclodextrins. Accordingly, the present claims are not obvious over the cited references.

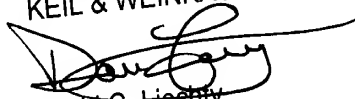
CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

A check in the amount of \$110.00 is attached to cover the required one month extension fee.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF


David C. Liechty
Reg. No. 48,692

1350 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 659-0100
DCL/kas

MARKED-UP VERSION SHOWING CHANGES MADE

IN THE CLAIMS

Please amend claim 1 to read as follows:

1. (currently amended) A process for producing solid dosage forms which are suitable for oral or rectal administration for humans and animals, wherein
 - a) 0.5 to 30% by weight of at least one active ingredient which is uncomplexed by cyclodextrin,
 - b) 0.5 to 70% by weight of at least one cyclodextrin selected from the group consisting of α -, β -, γ - or δ -cyclodextrins, the reaction products of cyclodextrins with alkylene oxide, alkyl halides, dialkyl sulfates, carbonyl chlorides, epihalohydrines, isocyanates or halogenated carboxylic acids, and polymer-modified cyclodextrins,
 - c) 10 to 98% by weight of at least one polymeric binder, selected from the group consisting of polyethylene glycol having a molecular weight above 4000, polyvinylpyrrolidone, and copolymers comprising N-vinylpyrrolidone and vinyl acetate, and
 - d) 0 to 50% by weight of conventional excipientsare mixed and plasticized at a temperature below 220°C without adding a solvent and the resulting plastic mixture is shaped to produce the dosage form.

COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

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1. (currently amended) A process for producing solid dosage forms which are suitable for oral or rectal administration for humans and animals, wherein
 - a) 0.5 to 30% by weight of at least one active ingredient which is uncomplexed by cyclodextrin,
 - b) 0.5 to 70% by weight of at least one cyclodextrin selected from the group consisting of α -, β -, γ - or δ -cyclodextrins, the reaction products of cyclodextrins with alkylene oxide, alkyl halides, dialkyl sulfates, carbonyl chlorides, epihalohydrines, isocyanates or halogenated carboxylic acids, and polymer-modified cyclodextrins,
 - c) 10 to 98% by weight of at least one polymeric binder, selected from the group consisting of polyethylene glycol having a molecular weight above 4000, polyvinylpyrrolidone, and copolymers comprising N-vinylpyrrolidone and vinyl acetate, and
 - d) 0 to 50% by weight of conventional excipientsare mixed and plasticized at a temperature below 220°C without adding a solvent and the resulting plastic mixture is shaped to produce the dosage form.
 2. (original) A process as claimed in claim 1, wherein the molar ratio between active ingredient and cyclodextrin is in the range from 0.1 to 4.0.
 3. (previously amended) A process as claimed in claim 1, wherein the plastic mixture is shaped in a molding calendar to produce the dosage forms.

4. (original) A process as claimed in claim 3, wherein a molding calender with counterrotating molding rolls is used, with at least one of the molding rolls having on its surface depressions to receive and shape the plastic mixture.
5. (previously amended) A solid dosage form which is essentially free of aliphatic C_2 - C_8 -di- and -tricarboxylic acids and aromatic C_6 - C_{10} -monocarboxylic acids, obtainable by a process as claimed in claim 1.
6. (original) A solid dosage form as claimed in claim 5, wherein at least 10% by weight of the active ingredient are present in the form of a cyclodextrin/active ingredient complex.
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